I. AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Currently Amended) A pharmaceutical composition comprising a matrix capable of delivering at least one therapeutic agent to a bodily compartment under controlled release conditions, said matrix comprising an emulsion of an aqueous phase and an oil phase, at least one therapeutic agent present in said aqueous phase, and at least one cross-linked polymer comprising a backbone selected from the group consisting of poly (alkylene oxide), carboxymethylcellulose, dextran, modified dextran, polyvinyl alcohol, N-(2-hydroxypropyl)methacrylamide, polyvinyl pyrrolidone, poly-1,3-dioxolane, poly-1,3,6-trioxane, polypropylene oxide, a copolymer of ethylene and maleic acid anhydride, a polyactide/polyglycolide copolymer, a polyaminoacid, a copolymer of poly(ethylene glycol) and an amino acid, and a polypropylene oxide/ethylene oxide copolymer, in said aqueous phase, physically entrapping said at least one therapeutic agent.

Claim 2-3. (Canceled)

Claim 4. (Cancelled)

Claim 5. (Original) The pharmaceutical composition of claim 1 wherein said polymer comprises at least two functional or reactive groups.

Claim 6. (Original) The pharmaceutical composition of claim 5 wherein said functional groups are amino, carboxyl, thiol, hydroxyl, or any combination thereof.

Claim 7. (Previously presented) The pharmaceutical composition of claim 6 wherein said polymer is a poly (alkylene oxide) derivative.

Claim 8. (Original) The pharmaceutical composition of claim 7 wherein said poly (alkylene oxide) derivative is selected from the group consisting of α,ω-dihydroxy-poly (ethylene glycol) and α,ω-diamino-poly (ethylene glycol).

Claim 9. (Original) The pharmaceutical composition of claim 6 wherein said functional groups are thiol groups.

Claim 10. (Original) The pharmaceutical composition of claim 9 wherein said polymer is prepared from α,ω-diamino-poly (ethylene glycol) and thiomalic acid; α,ω-dihydroxy-poly (ethylene glycol) and thiomalic acid; or α,ω-dicarboxy-PEG-subunits and lysine, wherein free carboxy groups on said lysine are derivatized to provide thiol groups.

Claim 11. (Original) The pharmaceutical composition of claim 9 wherein said thiol groups on said polymer are cross-linked by thioether or disulfide bonds.

Claim 12. (Original) The pharmaceutical composition of claim 9 wherein said thiol groups on said polymer are sterically hindered.

Claim 13. (Original) The pharmaceutical composition of claim 1 wherein said at least one therapeutic agent is selected from the group consisting of a small-molecule drug, a protein, a nucleic acid and a polysaccharide.

Claim 14. (Original) The pharmaceutical composition of claim 13 wherein said small molecule drug is selected from the group consisting of an anticancer drug, a cardiovascular drug, an antibiotic, an antifungal, an antiviral drug, an AIDS drug, an HIV-1 protease inhibitor, a reverse transcriptase inhibitor, an anti-nociceptive drug, a hormone, a vitamin, an anti-inflammatory drug, an angiogenesis drug, and an anti-angiogenesis drug.

Claim 15. (Original) The pharmaceutical composition of claim 1 wherein said matrix has at least one controlled release in-vivo kinetic profile selected from the group consisting of zero order, pseudo zero order, and first order.

Claim 16. (Original) The pharmaceutical composition of claim 1 wherein said controlled release conditions is a constant rate of release.

Claim 17. (Original) The pharmaceutical composition of claim 1 wherein said matrix further comprises an excipient.

Claim 18. (Original) The pharmaceutical composition of claim 17 wherein said excipient is selected from the group consisting of a monovalent metal ion, a polyvalent metal ion, an anionic polymer, a cationic polymer, a nonionic polymer, surfactant, and a protein.

Claim 19. (Currently Amended) A method for preparing a pharmaceutical composition comprising the steps of

i) preparing an emulsion of an aqueous phase and an oil phase, said aqueous phase comprising at least one therapeutic agent and a polymer comprising a backbone selected from the group consisting of poly (alkylene oxide), carboxymethylcellulose, dextran, modified dextran, polyvinyl alcohol, N-(2-hydroxypropyl)methacrylamide, polyvinyl pyrrolidone, poly-1,3-dioxolane, poly-1,3,6-trioxane, polypropylene oxide, a copolymer of ethylene and maleic acid anhydride, a polyactide/polyglycolide copolymer, a polyaminoacid, a copolymer of poly(ethylene glycol) and an amino acid, and a polypropylene oxide/ethylene oxide copolymer and having at least two functional groups thereon;

ii) cross-linking said polymer in said aqueous phase under conditions to form a cross-linked matrix having said therapeutic agent trapped therein.

Claim 20. (Original) The method of claim 19 wherein said functional groups are thiol groups.

Claim 21. (Original) The method of claim 20 wherein said conditions that cause crosslinking of said thiol groups comprises reaction in the presence of an oxidizing agent or reaction with a cross-linking agent.

Claim 22. (Original) The method of claim 21 wherein said oxidizing agent is selected from the group consisting of molecular oxygen, hydrogen peroxide, dimethylsulfoxide, and molecular iodine.

Claim 23. (Original) The method of claim 21 wherein said cross-linking agent is a bifunctional disulfide forming or thioether forming cross-linking agent.

Claim 24. (Original) The method of claim 23 wherein said cross-linking agent is selected from the group consisting of 1,4,-di-[3',2'-pyridyldithio(propionamido)butane], α,ω-di-O-pyridyldisulfidyl-poly(ethylene glycol); α,ω-divinylsulfone-poly(ethylene glycol); α,ω-diiodoacetamide-poly(ethylene glycol) and 1,11-bis-maleimidotetraethylene glycol.

Claim 25. (Previously presented) A method for delivering at least one therapeutic agent to a bodily compartment of an animal under controlled release conditions comprising providing in said bodily compartment a pharmaceutical composition of claim 1.

Claim 26. (Original) The method of claim 25 wherein said bodily compartment is subcutaneous, oral, intravenous, intraperitoneal, intradermal, subdermal, intratumor, intraocular, intravisceral, intraglandular, intravaginal, intrasinus, intraventricular, intrathecal, intramuscular, and intrarectal.

Claim 27. (Original) The method of claim 26 wherein said composition is provided to said bodily compartment by a route selected from the group consisting of subcutaneous, oral, intravenous, intraperitoneal, intradermal, subdermal, intratumor, intraocular,

intravisceral, intraglandular, intravaginal, intrasinus, intraventricular, intrathecal, intramuscular, and intrarectal.

Claim 28. (Previously presented) The method of claim 25 wherein said controlled release conditions occur as a consequence of diffusion from said matrix or biodegradation of said matrix by an in-vivo degradation pathway selected from the group consisting of reducing agents, reductases, S-transferases, peptidases, proteases, non-enzymatic hydrolysis, esterases, and thioesterases.

Claim 29. (Original) The method of claim 25 wherein said providing in said bodily compartment is carried out by forming said matrix immediately prior to or during administration of said matrix to said animal.

Claim 30. (Original) The method of claim 29 wherein said pharmaceutical composition is capable of being injected as a liquid or semisolid gel through a small gauge needle, begins cross-linking and entrapping said therapeutic agent during injection, and completes cross-linking and physically entrapping said therapeutic agent within minutes of being injected.

Claim 31. (Original) The method of claim 25, wherein said controlled release conditions comprise a time course of release of five or more days.

Claim 32. (Original) The method of claim 31, wherein said time course of release is twenty or more days.

Claim 33. (Original) The method of claim 25, wherein said releasing comprises a controlled release profile comprising an optional bolus release profile followed by a release profile selected from the group consisting of zero order, pseudo zero order, and first order.

Claim 34. (Previously presented) The method of claim 19, wherein said functional groups comprise two or more thiol-reactive groups, and; and wherein injecting a mammal with said emulsion provides for the formation of a hydrogel drug depot at the site of injection by said cross-linking of said polymer and having said therapeutic agent temporarily entrapped therein.

Claims 35-36. (Canceled)

Claim 37. (Canceled)

Claim 38. (Currently Amended) A controlled release composition for administration of a therapeutic agent to a mammal, comprising an emulsion of an aqueous phase and an oil phase, said aqueous phase containing a cross-linked hydrogel polymer matrix, and a lipid phase physically entrapped within said polymer matrix, said lipid phase having at least one therapeutically active agent contained therein, said hydrogel polymer matrix providing a controlled release of said therapeutically active agent when the composition is administered to a bodily compartment of a mammal, said polymer comprising a backbone selected from the group consisting of poly (alkylene oxide), carboxymethylcellulose, dextran, modified dextran, polyvinyl alcohol, N-(2-hydroxypropyl)methacrylamide, polyvinyl pyrrolidone, poly-1,3-dioxolane, poly-1,3,6-trioxane, polypropylene oxide, a copolymer of ethylene and maleic acid anhydride, a polyactide/polyglycolide copolymer, a polyaminoacid, a copolymer of poly(ethylene glycol) and an amino acid, and a polypropylene oxide/ethylene oxide copolymer.

Claim 39. (Previously presented) The pharmaceutical composition of claim 38 wherein said polymer comprises at least two functional or reactive groups selected from the group consisting of amino, carboxyl, thiol, hydroxyl, and any combination thereof.

Claim 40. (Previously presented) The pharmaceutical composition of claim 38, wherein said polymer is a poly (alkylene oxide) derivative.

Claim 41. (Previously presented) The pharmaceutical composition of claim 40 wherein said polymer is prepared from *a* ω-diamino-poly (ethylene glycol) and thiomalic acid; *a* ω-dihydroxy-poly (ethylene glycol) and thiomalic acid; or *a* ω-dicarboxy-PEG-subunits and lysine, wherein free carboxy groups on said lysine are derivatized to provide thiol groups.

Claim 42. (Previously presented) The pharmaceutical composition of claim 41 wherein said thiol groups on said polymer are cross-linked by thioether or disulfide bonds.

Claim 43. (Previously presented) The pharmaceutical composition of claim 38 wherein said at least one therapeutic agent is selected from the group consisting of a small-molecule drug, a protein, a nucleic acid and a polysaccharide.

Claim 44. (Previously presented) The pharmaceutical composition of claim 38 wherein said small molecule drug is selected from the group consisting of an anticancer drug, a cardiovascular drug, an antibiotic, an antifungal, an antiviral drug, an AIDS drug, an HIV-1 protease inhibitor, a reverse transcriptase inhibitor, an anti-nociceptive drug, a hormone, a vitamin, an anti-inflammatory drug, an angiogenesis drug, and an anti-angiogenesis drug.

Claim 45. (Previously presented) The pharmaceutical composition of claim 38 wherein said matrix has at least one controlled release in-vivo kinetic profile selected from the group consisting of zero order, pseudo zero order, and first order.

Claim 46. (Previously presented) The pharmaceutical composition of claim 38 which provides a constant rate of release of said therapeutically active agent when said pharmaceutical composition is administered to a mammal.

Claim 47. (Previously presented) The pharmaceutical composition of claim 38, wherein said cross-linked polymer is a polyalkylene oxide chemically modified to include thiol groups, reacted with a vinylsulfone cross-linking agent to form said matrix.

Claim 48. (Previously presented) The pharmaceutical composition of claim 39, wherein said cross-linked polymer is a diamino polyethyleneglycol crosslinked with a cross-linking agent selected from the group consisting of a bifunctional disulfide-forming cross-linking agent, a bifunctional thioether-forming cross-linking agent, and combinations thereof.

Claim 49. (Previously presented) The pharmaceutical composition of claim 38, wherein said therapeutically active agent is an antitumor agent, and the composition is in a form deliverable in proximity to a tumor.

Claim 50. (Previously presented) The pharmaceutical composition of claim 38, wherein said therapeutic agent diffuses at a controlled rate from said hydrogel polymer matrix in situ into said body compartment.

Claim 51. (Previously presented) The pharmaceutical composition of claim 1, wherein the therapeutic agent is a solid suspension in the aqueous phase.

Claim 52. (New) The pharmaceutical composition of claim 1, wherein said backbone is a poly(alkylene oxide).

Claim 53. (New) The pharmaceutical composition of claim 52, wherein said poly(alkylene oxide) is poly(ethylene glycol).

Claim 54. (New) The pharmaceutical composition of claim 1, wherein said backbone is a polyaminoacid.

Claim 55. (New) The controlled release composition of claim 38, wherein backbone is a poly(alkylene oxide).

Claim 56. (New) The controlled release composition of claim 55, wherein said poly(alkylene oxide) is poly (ethylene glycol).

Claim 57. (New) The controlled release composition of claim 38, wherein said backbone is a polyaminoacid.